

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Kevy *et al.*

Atty. Dock No.: 1459.008A

Serial No.: 10/765,694

Group Art Unit: 1657

Filing Date: January 27, 2004

Examiner: Laura J. Schuberg

Title: AUTOLOGOUS COAGULANT  
PRODUCED FROM WHOLE BLOOD

Confirmation No.: 1436

To: Commissioner for Patents<sup>1</sup>  
P.O. Box 1450  
Alexandria, VA 22313-1450

**RESPONSE TO NOTICE OF NON-COMPLIANT APPEAL BRIEF**

Dear Sir:

An Appeal Brief was filed January 25, 2011. A Notice of Non-Compliant Appeal Brief was mailed February 3, 2011, requesting Applicants to re-submit a Status of Claims section that identifies the status of all the claims. Further, Applicants are asked to provide support in the specification for the Summary of the Claimed Subject Matter section. Applicants are requested to provide an updated version of only these two sections, and not a revised Appeal Brief.

In response, Applicants note that the Appeal Brief outlined claims 1-18, 21 and 22 stand rejected and each of these rejected claims is being appealed. Applicants state that claim 19 is canceled and claim 20 is withdrawn; thus status of all claims are clear. A revised Status of

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<sup>1</sup> CERTIFICATE OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via EFS on February 9, 2011. /SF/

Claims section is provided herein. Further, Applicants provide a revised Summary of Claimed Subject Matter section, identifying supporting language from the specification.

No fee is believed due. The Commissioner is authorized to credit any overpayment, or charge any required fee to Deposit Account No. 08-1935.

Respectfully submitted,

*/s/ Shahrokh Falati*

Date: February 9, 2011

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**III. STATUS OF CLAIMS**

Appellant appeals under 35. U.S.C. § 134(a) from a rejection of claims 1-18, 21 and 22. Claims 1-18, and 21 and 22 stand rejected and each of these rejected claims is being appealed. Claim 19 stands canceled and claim 20 is withdrawn. A final Office Action was mailed April 26, 2010. A response to the final Office Action was filed on August 25, 2010. In response to an Advisory Action dated September 27, 2010, Applicants filed a Notice of Appeal on October 25, 2010. The Appeal Brief is filed on January 25, 2011. The appealed claims are attached as an Appendix.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention is directed to a method for the preparation of a stable autologous or homologous coagulant directly from whole blood. The direct precipitation of anticoagulated whole blood obviates the need for a plasma isolation step with unexpected results. The autologous or homologous coagulant produced by the method of the present invention demonstrated clotting times equivalent to commercially available bovine thrombin and human thrombin preparations, with improved kinetics of growth factor release from activated platelets over preparations of bovine thrombin.

There are two pending independent claims. Independent claim 1 is directed to a method for the production of thrombin from anticoagulated whole blood, comprising: (a) obtaining a volume of anticoagulated whole blood from a subject; (b) mixing said anticoagulated whole blood with ethanol at room temperature; (c) incubating the mixture of b) at room temperature for a time sufficient to produce a cellular and specific plasma component precipitate and a supernatant; (d) separating the precipitate from the supernatant; and (e) recovering the supernatant wherein said supernatant contains a thrombin preparation comprising 80-90% of prothrombin-thrombin proteins, no detectable fibrinogen and 20-30% of baseline levels of anti-thrombin III (ATIII).

Independent claim 22 is directed to a method for the production of a wound healing material, consisting of: a) obtaining a volume of anticoagulated whole blood from a subject; b) mixing said anticoagulated whole blood with ethanol at room temperature; c) incubating the mixture of b) at room temperature for a time sufficient to produce a cellular and specific plasma component precipitate and a supernatant; d) separating the precipitate from the supernatant; and

e) recovering the supernatant wherein said supernatant contains thrombin; and f) combining said supernatant with a blood derivative to form a wound healing material.

Support for the claimed subject matter can be found in the specification, for example, at pages 4-8, paragraphs [0014] to [0020], [0025] to [0030], page 14, paragraph [0042], and at page 37, paragraph [0098].